cliniminds™
Institute of Health Sciences Training & Management
AN ISO 9001:2015 Certified Academy

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ACCRE
Accreditation Council for Clinical Research Education

Post Graduate Diploma in Drug Regulatory Affairs

Regulatory professionals are the primary communication link between the company and global regulatory agencies such as USFDA (United States Food and Drug Administration) and European Union of Drug Regulatory Affairs (EUDRA).

The pharmaceutical, biotechnology and medical device research and development industries are among the most highly regulated industries globally. As pharmaceutical sector is growing rapidly, there is a need of regulatory affairs professionals to cater the current needs of industries for the global competition. Regulatory affairs professionals are the link between pharmaceutical industries and worldwide regulatory agencies. Pharmaceutical Industry, being one of the highly regulated industries, is in immense need of people than ever before who are capable of handling issues related to regulatory affairs in a comprehensive manner

Cliniminds has been at the forefront of providing clinical research training and consulting solutions to the life sciences industry for the last several years. We have already trained over 8,000 professionals and successfully placed them in the industry. Cliniminds boasts of various programs, running for the last 15+ years and over 100 batches have passed and have been placed in the pharmaceutical companies, CROs, KPOs and other clinical research organizations. Our students have been placed with the leading companies.

Program Details **:** The program would cover

Module – 1

- Introduction to Regulatory Affairs
- Pharma Regulations Practices and Procedure
- Global Pharmaceutical Industry Scenario
- Indian Pharmaceutical Industry
- Global Regulatory Environment
- Regulations Governing Clinical Trials and New Drugs
- Schedule Y
- Regulatory Inspections in Clinical Research (FDA, EMEA, UK and Indian)
- Future of Regulatory Compliance
- Orphan Drugs

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India | Canada | US | UK | Saudi Arabia | Philippines |

Module-2

- Import and Export of Drugs
- Good Manufacturing Practice
- Quality Assurance and Regulations
- Global Drug Policies
- Regulation in Pharmaceutical Devices
- Test
- TRIPPs and Pharma Industry
- Intellectual Property Right Management
- Patents
- Pharmacovigilance (Introduction, global reporting requirements)

Eligibility : MD, MS, MBBS, BDS, BHMS, BAMS, BUMS, BPT, B.Pharms, Graduate/Post Graduate Degree in Life Sciences, Mathematics, Pharmacology, Pharmacy, Medical Laboratory, Nursing, Biochemistry, Microbiology, Biotechnology and all professionals working with Pharmaceutical companies, CROs and Hospitals.

Methodology : Online Training Modules; Online learningSystem

Examination : Online MCQs

Certificate : Certificate would be awarded upon successful completion of the program. Program is Certified & Accredited by the **Pharmaceutical Society ofIndia.**

Accreditation : Accreditation would be awarded upon successful completion of the program. Program is Certified & Accredited by **Accreditation Council for Clinical Research Education, US.**

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Fee payment: Fee Payable by Cash, Cheque/Bank draft in the name of **"TENET HEALTH EDUTECH PVT LTD."** Payable at Delhi Fee can also be deposited in company bank account. We also accept Credit/Debit Cards.

International Payments : Through Debit/Credit cards using Paypal or wire payment through banks

Course Objectives

- Concepts and importance of Drug Regulatory Guidelines
- Learn the skills, knowledge and competencies of a candidate for the drug regulatory jobs.
- Become more familiar with roles/jobs as part of the regulatory affairs team.
- Understanding of all drug development, marketing and post marketing regulatory issues
- Basic concepts, importance of Regulatory Guidelines

Technology & Knowledge Partners

AB-Cube More than softwares | TARA | ADVERA HEALTH ANALYTICS | CLINEVO Technologies | Think i | CRQA Clinical Regulatory Quality Assurance

Cliniminds, Unit of Tenet Health Edutech Pvt. Ltd.

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